

Appendix: Quality Assurance Guidelines for Testing Using Waived Rapid HIV Antibody Tests

Overview

This appendix includes several items to facilitate conducting testing and quality assurance activities using waived rapid HIV antibody tests. The forms provided are examples and templates that can be adapted for local use, adding or deleting fields, as needed. The appendix includes the following:

- A. Government regulations
 - B. Training checklist for waived rapid HIV antibody testing
 - C. Temperature log
 - D. Log of quality control results
 - E. Log of test results
 - F. Specimen transfer log
 - G. External assessment: proficiency testing and other evaluation programs
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Appendix A Government Regulations

Food and Drug Administration (FDA) sales restrictions

To help ensure the quality of testing, the FDA has approved rapid HIV tests with specific sales restrictions. By purchasing the test, the customer agrees to follow these restrictions. The restrictions are outlined below (for specific FDA language, refer to the package insert for the test being used). The kit purchaser must:

- Be a clinical laboratory, i.e., holds a certificate from the Federal government (Clinical Laboratory Improvement Act of 1988 (CLIA) certificate – see below for details) and any state or other certification that is required.
- Have an established quality assurance program.
- Provide training for testing personnel (operators) using the instructional materials provided by the manufacturer.
- Provide information to persons being tested by giving each a copy of the manufacturer’s “Subject Information” pamphlet prior to specimen collection and appropriate information when providing the test results.
- Not use the kit to screen blood or tissue donors.

Clinical Laboratory Improvement Amendment (CLIA) regulations

Federal regulations for waived tests (CLIA regulations) are minimal. The CLIA requirements for sites wishing to offer testing are listed below and can be found at <http://wwwn.cdc.gov/clia/regs/toc.aspx>. Each site must:

- Have a valid CLIA Certificate of Waiver, Certificate of Compliance or Certificate of Accreditation or be included under a multi-site certificate.
 - Follow the manufacturer’s instructions for performing the test, and
 - Permit announced or unannounced inspections by representatives of the Centers for Medicare & Medicaid Services (CMS) under certain circumstances.
 - Perform only waived tests if holding a Certificate of Waiver.
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Government Regulations, continued

How to obtain a CLIA certificate

All sites planning to offer waived rapid HIV testing not already CLIA-certified, must obtain a Certificate of Waiver or be included under a multiple site exception, such as limited public health testing or mobile testing. To obtain a Certificate of Waiver, complete Form CMS-116, found at the following CMS Internet address: <http://www.cms.hhs.gov/CLIA>. This form asks for information on the facility type (select from a list), hours of operation, estimated annual number of waived tests to be performed, the type of control (nonprofit, for profit or government control) and the total number of individuals involved in performing testing. The facility owner or laboratory director must sign the form. Mail the completed form to the designated State agency for the state where your site is located. To find your State agency contact, refer to the information provided at the following Internet address <http://www.cms.hhs.gov/CLIA>. After the completed form is processed by the State agency, a fee of \$150 will be assessed for a Certificate of Waiver. The certificate is valid for two years.

State regulations

In addition to CLIA, some States have specific regulatory requirements for HIV testing. Contact your State agency for information on State requirements. State agency contacts are listed at <http://www.cms.hhs.gov/CLIA>.

Occupational safety and health regulations

Employers with employees who have an occupational exposure to blood or other potentially infectious materials must meet the U.S. Department of Labor Occupational Health and Safety Administration (OSHA) standards for bloodborne pathogens. Individuals collecting blood specimens or performing rapid HIV testing have exposure to blood or other potentially infectious materials resulting from the performance of their duties. Therefore, sites offering rapid HIV testing must meet OSHA standards that include, but are not limited to, the following requirements:

- Have a written Exposure Control Plan.
- Provide personal protective equipment, such as gloves.
- Make available the hepatitis B vaccine and vaccination series to all employees who have occupational exposure.
- Provide post-exposure evaluation and follow-up to all employees who have had an exposure incident.
- Provide training for all employees with occupational exposure.
- Contain and dispose of biohazard waste following applicable regulations (includes blood and items contaminated with blood or other potentially infectious materials). Refer to state and local regulations regarding disposal of biohazardous materials.

NOTE: This is an overview of OSHA requirements and is not a complete list. For specific information, visit the OSHA Web site at <http://www.osha.gov/SLTC/bloodbornepathogens/index.html>.

Appendix B

Example Training Checklist for Waived Rapid HIV Antibody Testing

Employee: *(Name)* _____

Instructions: Fill in dates when the trainee observes and performs each objective or procedural step, as applicable. (If a trainee will not perform a specific task, enter N/A for not applicable.) The trainee should initial when he/she feels the objective/procedure has been mastered and the trainer when he/she thinks the trainee has met the objective or performs the specific procedure competently.

Objective/Procedural Step	Date Observed	Date Performed	Trainee's initial and date	Trainer's initial and date
Read test procedure	N/A			
Read Biohazard Exposure Control Plan	N/A			
Determine if requirements for acceptable testing environment are met (e.g., temperature, lighting, level work space)				
Practice test with negative and positive external controls				
Give person being tested the "Subject Information" brochure				
Label test device components and appropriate paperwork				
Collect blood specimen and/or oral fluid using proper collection technique				
Load test device, add reagents, time test, and read result correctly				
Dispose of lancet and other biohazardous waste appropriately				
Record results on report form and log sheet				
Record internal and external quality control (QC) results in QC log				
Evaluate a new test kit lot number and record results in QC log				
Report test result to the person being tested (one negative and one preliminary positive)				
Refer person or collect specimen for confirmatory testing				
Send confirmatory test specimen to referral laboratory and document submission				
Receive referral laboratory results and record results				
Explain what to do if QC results show a problem				

Appendix C Example Temperature Log

Thermometer location _____

Acceptable temperature range* _____

Month/Year _____

Day	Temperature	Initials	Day	Temperature	Initials
1			17		
2			18		
3			19		
4			20		
5			21		
6			22		
7			23		
8			24		
9			25		
10			26		
11			27		
12			28		
13			29		
14			30		
15			31		
16					

* Refer to the package insert for the acceptable range for test kit and control kit storage and the acceptable range for the testing area.

NOTE: Periodically (e.g., every six months) check thermometer performance and document. “Min-Max” thermometers maintain a record of the highest and lowest temperature recorded during an observation period and are highly recommended.

Corrective Action

Date	Action Taken	Initials

Reviewed by and date

Appendix D

Example Log of Control Results

Date	Time	Test Kit Lot #	Test Kit Exp. Date*	New Lot #, shipment?	Control Kit Lot #	Control Kit Exp. Date	Date controls opened	Negative Control Result	Positive Control Result	Results Acceptable?	Performed by	Reviewed by and Date

*Exp. = Expiration

Corrective Action (use reverse side, if needed)

Date	Action Taken	Initials	Reviewed by and Date

Appendix G

External Assessment: Proficiency Testing and Other Mailed Evaluation Programs

Background and overview Some States may require participation in a State or Centers for Medicare & Medicaid Services (CMS)-approved proficiency testing (PT) program, even though participation in PT is not required by CLIA for waived tests. Participating in proficiency testing or an external evaluation program is a relatively easy way to obtain an external assessment of the quality of testing. There are several programs in which a site may choose to enroll. Test samples are received by mail on a periodic basis, usually two to three times per year. Program shipments include a combination of several (typically five) HIV antibody positive and negative challenge samples with results known to the program provider, but not to the participants. The participants test the samples as if they were client/patient specimens and send results back to the program provider.

Evaluation reports In proficiency testing programs, the results from the individual participant sites are compared to the expected values. Each site receives a graded individualized report and summary report showing their performance and the performance of all the participants. In some evaluation programs, such as the Model Performance Evaluation Program (MPEP) offered by the Centers for Disease Control and Prevention (CDC), individual participant results are not graded; instead a summary report is provided with a compilation of results from all participants and a commentary on overall performance.

For more information For more information, refer to the following Internet sites:

- For more information on the CDC MPEP for rapid HIV testing and to enroll on-line go to the following Web sites:
<http://wwwn.cdc.gov/mpep/default.aspx>.
There is currently no fee to enroll in the MPEP program; however, enrollment is limited.
- For a list of CLIA-approved PT programs (several of which include HIV testing) go to <http://www.cms.hhs.gov/CLIA> . This list includes contact information for each program and the tests offered. These programs charge an enrollment fee.
